IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
AMGEN INC. and AMGEN MANUFACTURING LTD.	)	
Defendants.	)	

COMPLAINT

INTRODUCTION

1. This is an action for patent infringement arising from Amgen's desire to reap the rewards of AbbVie's innovation. This innovation has resulted in more than 100 issued United States patents concerning the HUMIRA® product, 61 of which AbbVie has identified as infringed. Whereas AbbVie has spent decades of research and vast resources on the development of HUMIRA®, Amgen seeks to copy AbbVie's work and ignore AbbVie's patents. But while the Biosimilar Price Competition and Innovation Act ("BPCIA") gives Amgen an abbreviated regulatory pathway for its biosimilar version of HUMIRA®, it does *not* give Amgen license to infringe AbbVie's patents. AbbVie seeks an injunction to prevent this blatant infringement.

2. HUMIRA® is in a category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. These are critically important drugs that are difficult to develop, manufacture, formulate, and administer. Within the category of biologics, HUMIRA® is unique. HUMIRA® was the first fully human antibody

approved by the Food and Drug Administration ("FDA"). In bringing HUMIRA® from the laboratory to patients, AbbVie was operating in uncharted territory. In 1996, AbbVie invented the antibody. But that was only the first step. Since then, AbbVie has embarked on two decades of research, investment, and innovation.

3. As part of its commitment to improve patients' lives, AbbVie has dedicated substantial resources to an extensive clinical trial program. AbbVie's clinical research on HUMIRA® includes over 100 clinical trials and resulted in FDA approval for the treatment of ten different diseases, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis, and juvenile idiopathic arthritis. To date, over one million patients have benefited from AbbVie's pioneering work on HUMIRA®. Amgen seeks to copy the results of AbbVie's clinical development.

4. To further benefit patients, AbbVie has also invested in creating a subcutaneous, high concentration, liquid formulation. Before AbbVie's launch of HUMIRA®, patients had to go to the hospital to receive their medicine intravenously or mix batches of their medicine at home (which was difficult for patients with inflamed joints) and inject themselves twice a week. As a result of AbbVie's dedication and innovation, patients can now inject the medicine at home, using pre-filled syringes, and take fewer injections. The added convenience and precision has improved patients' lives and increased compliance, all without sacrificing HUMIRA®'s outstanding efficacy. Here again, Amgen seeks to copy the results of AbbVie's innovative formulation work.

5. AbbVie has also spent many years understanding the complex manufacturing process for HUMIRA®. As discussed above, unlike traditional drugs, HUMIRA® is a complex biologic created in living organisms. Even minor changes can impact the stability, purity, and

efficacy of the drug. Again, Amgen seeks to copy the results of AbbVie's innovative manufacturing work.

6. In attempting to copy the results of AbbVie's innovations, however, Amgen is faced with three major hurdles: the United States Patent and Trademark Office ("Patent Office") has granted AbbVie numerous patents which are valid and infringed by Amgen, the United States Congress has laid out a mechanism for AbbVie to bring litigation on these patents before Amgen launches its biosimilar, and Amgen's positions in this case are contrary to positions it has previously taken.

7. First, the Patent Office has recognized AbbVie's innovative work beyond the invention of the HUMIRA® antibody itself, granting AbbVie 100 patents, 61 of which are at issue between the parties. There is no question that Amgen infringes AbbVie's patents; it does not even dispute this fact with respect to many of AbbVie's patents. And there is also no question that AbbVie's patents are valid. Indeed, just last year, Amgen asked the Patent Office to invalidate two of AbbVie's patents that cover Amgen's proposed formulations. The Patent Office found that Amgen had failed to establish a reasonable likelihood that *any* of the challenged claims of those patents were invalid and *refused to even initiate* the proceedings. Simply put, Amgen's knock-off product infringes AbbVie's patents, and AbbVie's patents are valid.

8. Second, in the BPCIA, Congress recognized the need to protect an originator's patent rights and provided a multi-step process for identifying and litigating those patents. As part of that process, AbbVie identified 61 patents, but this lawsuit involves only 10 of them. That is Amgen's choice, not AbbVie's. The BPCIA gave Amgen the ability to cap the number of patents at issue in this lawsuit, rather than litigate all of AbbVie's patents efficiently in a

single wave and without delay. As spelled out in the law, Amgen selected the number of patents (6) each side could litigate in this first wave, the parties exchanged lists of 6 patents each, and the patents-in-suit constitute the compilation of the two lists (2 patents were on both lists). But Amgen has only delayed its day of reckoning with respect to the vast majority of AbbVie's patents. It cannot avoid them indefinitely. While AbbVie is only permitted to assert 10 patents now, if and when Amgen provides its 180 day Notice of Commercial Marketing, and as circumstances otherwise warrant, AbbVie will assert the remainder of the patents. Therefore, there will be a second wave of litigation to adjudicate AbbVie's substantial patent rights relating to HUMIRA®.

9. Third, in seeking to defend its copycat actions here, Amgen is speaking out of both sides of its mouth. When biosimilars attempt to knock off *its* biologic products, Amgen tells a different story. Amgen has repeatedly recognized how difficult it is to innovate methods of using, formulating, and manufacturing biologics. Indeed, Amgen has made arguments to the Patent Office that are directly at odds with those it is advancing in this case in order to secure numerous patents covering methods of using, formulating, and manufacturing drugs (especially biologic drugs). And when biosimilars seek to reap the rewards of Amgen's works, Amgen has declared that they are "piggybacking on the fruits" of innovators' "trailblazing efforts." *Amgen Inc. v. Sandoz Inc.*, Case No. 3:16-cv-02581 (N.D. Cal.), Complaint ¶ 72 (D.I. 1). While Amgen may hope to profit by straddling the fence, it should be held to the positions it has taken in procuring its own patents and litigating those patents against biosimilars.

10. AbbVie seeks an injunction to prevent Amgen from engaging in widespread infringement of the 10 patents in this Complaint. AbbVie also reserves its right to assert the

remaining patents infringed by Amgen in a second wave if and when Amgen provides a Notice of Commercial Marketing, or as circumstances otherwise warrant.

NATURE OF THE ACTION

AbbVie Inc. and AbbVie Biotechnology Ltd. (together "AbbVie" or "Plaintiffs") for their Complaint against Defendants Amgen Inc. and Amgen Manufacturing Ltd. ("Amgen" or "Defendants") further allege as follows:

11. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2)(C). This is also a civil action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 seeking a declaratory judgment to compel Amgen to comply with 42 U.S.C. § 262(*l*)(8)(A) of the BPCIA.

12. This lawsuit results from Amgen's infringement of AbbVie patents that concern AbbVie's groundbreaking HUMIRA®.

13. AbbVie Inc. is the holder of Biologic License Application ("BLA") No. 125057 for HUMIRA®, whose active pharmaceutical ingredient is the antibody adalimumab.

14. In 1996, after many years of intense research, AbbVie's predecessor first created adalimumab. Adalimumab, a biologic, is a fully human, high-affinity and neutralizing therapeutic antibody to human TNF-α, a protein made by the human body as part of the body's immune response. The mechanisms by which TNF-α affects the body are complex and not completely understood (even today).

15. The invention of adalimumab was particularly noteworthy in that it was the first fully human antibody approved by the FDA. This was hailed by the medical and scientific community as a major breakthrough. Compared to other drugs that were available at the time, adalimumab offered patients substantial benefits. For example, REMICADE® (infliximab),

which was a chimeric antibody, had numerous drawbacks, including, among others, the fact that it had to be administered by intravenous injection at an infusion center.

16. Inventing the antibody itself, however, was only the first step in the process. Following the isolation and characterization of adalimumab, AbbVie and its predecessor Abbott Laboratories, spent decades and hundreds of millions of dollars on scientific studies and clinical trials to determine how to use HUMIRA® to treat patients for different diseases, how to formulate HUMIRA® for administration to humans, and how to manufacture HUMIRA®. AbbVie's scientific and clinical investments in HUMIRA® continue to this day.

17. AbbVie's innovative work has been recognized by the medical and scientific community. For example, in 2007, HUMIRA® was awarded the Galen Prize, perhaps the most prestigious honor in the pharmaceutical and biotechnology world.

18. More importantly, AbbVie's work has benefited patients immensely. Children have gone from wheelchairs to playgrounds, and adults have gone from bed to work. AbbVie is very proud of the fact that HUMIRA® has helped more than one million patients to date.

19. The Patent Office has also recognized AbbVie's innovative work by granting it over 100 patents on HUMIRA® beyond the initial compound patent, 61 of which AbbVie has identified as infringed by Amgen.

20. Amgen has chosen to allow AbbVie to bring this lawsuit on only 10 of AbbVie's 61 patents at this time. While Amgen can delay justice, it cannot prevent it. Pursuant to the BPCIA, AbbVie can seek relief, including an injunction, on the remaining 51 patents when Amgen files a Notice of Commercial Marketing, which it must do at least 180 days prior to launching its biosimilar product.

21. In seeking approval for its biosimilar adalimumab product ABP 501 (the "Amgen aBLA Product"), Amgen seeks to benefit from AbbVie's substantial investment in HUMIRA® and the two decades of time, effort, investment, and innovation by AbbVie's scientists. Although the BPCIA allows Amgen an abbreviated regulatory pathway, it does not give Amgen a license to infringe AbbVie's intellectual property. At this time, AbbVie seeks an injunction to prevent infringement of at least 227 claims of the 10 asserted AbbVie patents. If and when Amgen files a Notice of Commercial Marketing or as circumstances otherwise warrant, AbbVie will assert additional patents from its estate.

PARTIES

22. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs.

23. Plaintiff AbbVie Biotechnology Limited is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM1l, Bermuda. Through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff AbbVie Biotechnology Limited.

24. Upon information and belief, Defendant Amgen Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen is a company that is, *inter alia*, engaged in the development of biologic drugs, including a proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, ABP 501.

25. Upon information and belief, Defendant Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. Upon information and belief, Defendant AML is a wholly-owned subsidiary of Defendant Amgen Inc.

26. Upon information and belief, AML is a company that is, *inter alia*, engaged in the manufacture of biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, ABP 501, that is the subject of Defendant Amgen's aBLA. Upon information and belief, these drugs are (or will be) distributed and sold in the State of Delaware and throughout the United States.

27. Upon information and belief, Defendant AML is working in concert with Defendant Amgen Inc. with respect to the regulatory approval of a proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product and Defendant AML intends to benefit directly from any approval of the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product.

JURISDICTION AND VENUE

28. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

29. This court has jurisdiction over Defendant Amgen Inc. because, *inter alia*, it is incorporated in the State of Delaware.

30. This court has jurisdiction over Defendant AML because it has, through cooperative activity with Defendant Amgen Inc., engaged in sufficient conduct both within and without the State of Delaware.

31. Upon information and belief, Defendant AML has acted in concert with Defendant Amgen Inc. to develop a biosimilar version of HUMIRA®. Upon information and belief, Defendant AML has acted in concert with Defendant Amgen Inc. to file an aBLA seeking FDA approval to market and sell the Amgen aBLA Product in the State of Delaware and throughout the United States, which directly gives rise to AbbVie's claims of patent infringement.

32. Upon information and belief, Defendant AML manufactured the Amgen aBLA Product lots that were used in clinical trials. *See* Amgen, Background Information for the Arthritis Advisory Committee 12 July 2016, at 34, attached hereto as Exhibit 2. The results of those clinical trials were included in the aBLA and were presented to the FDA Arthritis Advisory Committee on July 12, 2016. *See* Exhibit 2, at 63-94; Press Release, Amgen, "Amgen to Discuss Data Supporting Biologics License Application for ABP 501, A Biosimilar Candidate to Adalimumab (July 12, 2016), attached hereto as Exhibit 3. Upon information and belief, Defendants have worked in concert to validate the manufacturing process for the Amgen aBLA Product and to ensure that it meets the process performance and product quality expectations necessary for regulatory approval. *See* Exhibit 2 at 34-35.

33. Upon information and belief, Defendant AML directly or indirectly manufactures pharmaceutical products which Defendant Amgen Inc. then markets and sells in Delaware and throughout the United States. Upon information and belief, Defendant AML, in concert with Defendant Amgen Inc., intends to manufacture the Amgen aBLA Product for marketing and sale into Delaware if the Amgen aBLA Product receives FDA approval.

34. Additionally and alternatively, to the extent Defendant AML is not subject to the jurisdiction of the courts of general jurisdiction of the State of Delaware, Defendant AML is likewise not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Federal Rule of Civil Procedure 4(k)(2).

35. Venue lies in this District pursuant to 28 U.S.C. § 1391(b).

THE PARTIES' EXCHANGES UNDER THE BPCIA

36. Upon information and belief, on November 25, 2015, Amgen submitted an abbreviated Biologics License Application ("aBLA") to the FDA pursuant to the Biosimilar Price Competition and Innovation Act ("BPCIA"), specifically 42 U.S.C. § 262(k), requesting that its biosimilar adalimumab product ABP 501 be licensed for commercial sale by relying on AbbVie's demonstration that HUMIRA® is safe, pure, and potent. The BPCIA provides an abbreviated pathway for approval of a biologic product that is "biosimilar" to a "reference product." Upon information and belief, on or about January 22, 2016, the FDA accepted Amgen's aBLA.

37. To facilitate the protection of biologic innovator's patent rights, Congress created an act of infringement related to the submission of an application under subsection 262(k), *see* 35 U.S.C. § 271(e)(2)(C), and enumerated a set of pre-litigation exchanges under the BPCIA which are outlined at 42 U.S.C. § 262(*l*). The subsection *(l*) procedures are intended to ensure that the maker of an innovative biologic product that is the subject of a biosimilar application will have sufficient time and opportunity to enforce its patent rights before a biosimilar product enters the market. The BPCIA also requires that upon FDA approval, a subsection (k) applicant give at

least 180 days' notice before the first commercial marketing of a biosimilar licensed by the FDA. 42 U.S.C. § 262(*l*)(8)(A). The statute specifically contemplates injunctive relief, including preliminary injunctive relief, to prevent unlawful infringement.

38. On January 26, 2016, AbbVie asked Amgen to confirm that it would provide both its aBLA and other manufacturing information pursuant to 42 U.S.C. § 262(*l*)(2)(A) so that AbbVie could evaluate the extent of Amgen's infringement of AbbVie's patents. In February 2016, the parties began exchanging information in accordance with the procedures outlined in the BPCIA. Although Amgen provided its aBLA to AbbVie, it did not provide any "other information that describes the process or processes used to manufacture" ABP 501 as required by the statute. 42 U.S.C. § 262(*l*)(2)(A). In addition, Amgen refused to enter into a confidentiality agreement that would have given AbbVie's outside expert witnesses access to Amgen's aBLA or to expand the number of AbbVie in-house counsel who could review the aBLA beyond the single person allowed by statute.

39. On April 11, 2016, pursuant to 42 U.S.C. § 262(*l*)(3)(A), AbbVie provided Amgen with a list of patents (and allowed patent applications) for which it believed a claim of patent infringement could be reasonably asserted against Amgen's adalimumab biosimilar ("AbbVie's 3A List"). This list identified 61 patents and 5 allowed patent applications (which have since been granted), from among the more than 100 patents in the HUMIRA® estate. AbbVie also asked, "in the event that Amgen asserts that any claims of these patents (or applications) are either not infringed or invalid pursuant to Section (l)(3)(B)(ii)(I), . . . that Amgen identify and provide copies of any documentary evidence supporting those assertions, so that AbbVie may fully consider it." Again, Amgen provided no additional evidence to support non-infringement of the listed patents.

40. On April 25, 2016, pursuant to 42 U.S.C. § 262(*l*)(7), AbbVie provided a supplemental patent list adding a recently issued patent (which had been one of the 5 allowed patent applications on AbbVie's 3A List), and on May 2, Amgen agreed to treat all 5 allowed patent applications on AbbVie's 3A List as part of AbbVie's patent list for all purposes. On May 10, 2016, AbbVie provided a second supplemental patent list adding two recently issued patents (both of which had been listed as patent applications on AbbVie's 3A List). And on June 9, 2016, AbbVie provided a third supplemental patent list, identifying two more recently issued patents (the last two patent applications from AbbVie's 3A list).

41. On June 10, 2016, Amgen responded by providing AbbVie with a statement contesting Amgen's infringement of certain patents and the validity of those patents. *See* 42 U.S.C. § 262(*l*)(3)(B). Despite AbbVie's requests, Amgen did not provide any additional evidence (*e.g.*, additional manufacturing documents or product information, beyond what was in the aBLA) relating to its non-infringement contentions. Nor did it provide any copies of the invalidity references it is relying on, some of which were incorrectly identified and/or dated. Amgen's statement was deficient in other respects as well. For example, Amgen's statement repeatedly cites to alleged evidence of non-infringement from its aBLA which, when checked, either does not support the proposition for which it is cited, or in some cases, flatly contradicts it. Further, Amgen identified numerous references as alleged prior art without providing an explanation of what the reference disclosed or how it rendered any claim anticipated or obvious.

42. On June 21, 2016, AbbVie responded in accordance with 42 U.S.C. § 262(*l*)(3)(C) by providing Amgen with a nearly 1,500 page statement showing that Amgen's biosimilar ABP 501 product would infringe more than 1,100 claims of the following 60 AbbVie patents and that those patent claims were valid ("AbbVie's 3C Statement"):

U.S. Patent No.	Title
6,090,382	Human Antibodies that Bind Human TNFα
8,889,135	Methods of Administering Anti-TNFα Antibodies
9,017,680	Methods of Administering Anti-TNFα Antibodies
9,073,987	Methods of Administering Anti-TNFα Antibodies
8,911,737	Methods of Administering Anti-TNFα Antibodies
8,974,790	Methods of Administering Anti-TNFα Antibodies
8,992,926	Methods of Administering Anti-TNFα Antibodies
8,889,136	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
8,961,973	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
8,961,974	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
9,061,005	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
9,187,559	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
8,986,693	Use of TNFα Inhibitor for Treatment of Psoriasis
9,090,689	Use of TNFα Inhibitor for Treatment of Psoriasis
8,906,373	Use of TNF-Alpha Inhibitor for Treatment of Psoriasis
9,085,620	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
9,067,992	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
8,715,664	Use of Human TNFα Antibodies for Treatment of Erosive Polyarthritis
8,808,700	Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis
8,999,337	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα
9,284,370	Methods for Treating Juvenile Idiopathic Arthritis
8,926,975	Method of Treating Ankylosing Spondylitis
8,802,100	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
8,802,101	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
8,916,157	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
8,916,158	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
9,114,166	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
9,220,781	Formulation of Human Antibodies for Treating TNF-α Associated Disorders

U.S. Patent No.	Title
9,272,041	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
9,302,011	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
9,096,666	Purified Antibody Composition
9,102,723	Purified Antibody Composition
9,273,132	Purified Antibody Composition
8,916,153	Purified Antibody Composition
8,895,009	Purified Antibody Composition
8,883,156	Purified Antibody Composition
8,906,372	Purified Antibody Composition
9,328,165	Purified Antibody Composition
8,231,876	Purified Antibody Composition
8,663,945	Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture
8,906,646	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
8,911,964	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
9,073,988	Fed Batch Method of Making Anti-TNF-Alpha Antibodies
9,090,867	Fed-Batch Method of Making Anti-TNF-Alpha Antibody
9,234,032	Fed-Batch Methods for Producing Adalimumab
9,284,371	Methods of Producing Adalimumab
9,206,390	Methods to Control Protein Heterogeneity
9,290,568	Methods to Control Protein Heterogeneity
9,234,033	Methods to Control Protein Heterogeneity
9,085,618	Low Acidic Species Compositions and Methods for Producing and Using the Same
9,200,069	Low Acidic Species Compositions and Methods for Producing and Using the Same
9,200,070	Low Acidic Species Compositions and Methods for Producing and Using the Same
9,334,319	Low Acidic Species Compositions
9,315,574	Low Acidic Species Compositions and Methods for Producing and Using the Same
9,346,879	Protein Purification Methods to Reduce Acidic Species
9,150,645	Cell Culture Methods to Reduce Acidic Species
9,359,434	Cell Culture Methods to Reduce Acidic Species
9,266,949	Low Acidic Species Compositions and Methods for Producing and Using the Same
9,255,143	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins

U.S. Patent No.	Title
9,018,361	Isolation and Purification of Antibodies Using Protein A Affinity Chromatography

43. AbbVie also identified 6 patents that it was no longer pursing an infringement claim on.

44. On June 22, 2016, AbbVie provided a supplemental patent list pursuant to 42 U.S.C. § 262(*l*)(7) adding recently issued patent U.S. Patent No. 9,365,645. This brought the total number of patents asserted by AbbVie against Amgen to 61.

AMGEN'S REFUSAL TO NEGOTIATE IN GOOD FAITH

45. Despite the clear mandate of the BPCIA and repeated entreaties by AbbVie, Amgen refused to engage in good faith negotiations over which patents should be the subject of this litigation. *See* 42 U.S.C. § 262(*l*)(4)(A). Those negotiations should have started immediately after Amgen received AbbVie's 3C Statement. *See id*; *Amgen v. Sandoz*, C.A. No. 2:16-cv-01276 (D.N.J. July 22, 2016) ("Under (l)(3)(c), the parties shall negotiate in good faith to identify the patents that will be the subject of an immediate action for patent infringement *for the 15 days after the RPS replies to the § 262(k) applicant*. *Id*. § 262(l)(4)(A).") (emphasis added). Instead, Amgen refused to begin negotiations until nearly one month later, on July 15.

46. The same day that it provided its 3C Statement, and that negotiations were supposed to have begun under the statute, AbbVie provided Amgen with its opening proposal that the parties litigate all the identified patents in this suit. AbbVie restated its proposal on June 30, and again on July 26, explaining that litigating all the patents at issue in this suit furthered the interests in judicial economy, by avoiding two waves of litigation. Despite knowing AbbVie's position well in advance of the negotiations, Amgen refused to provide any counter-proposal

during the negotiation period. Amgen instead waited until the last day possible to provide AbbVie with the number of patents that it would agree to be sued on. That number was six. This meant that the maximum number of patents that could be part of this first lawsuit under the BPCIA was twelve (six patents from each side), despite AbbVie's identification of 61 patents in the BPCIA exchange process.

47. On August 4, 2016, the parties exchanged their lists of 6 patents pursuant to 42 U.S.C. § 262(l)(5). AbbVie identified United States Patent Nos. 8,911,964; 8,916,157; 8,986,693; 8,961,973; 9,096,666; and 9,272,041. Amgen identified United States Patent Nos. 8,663,945; 8,986,693; 9,096,666; 9,220,781; 9,359,434; and 9,365,645. Given there was overlap of 2 patents, there are 10 patents in this suit.

48. At this time, and as a result of Amgen's gamesmanship and delay throughout the exchange and negotiation process, AbbVie is limited to seeking redress on 10 of its 61 infringed patents. But AbbVie will have a second opportunity, if and when Amgen provides a 180-day Notice of Commercial Marketing (or as circumstances otherwise warrant), to assert its remaining patents. So while Amgen's tactics may create delay, it still must deal with AbbVie's patents before going to market.

AMGEN'S aBLA PRODUCT

49. Upon information and belief, Amgen submitted its aBLA for ABP 501 to the FDA on November 25, 2015. In a press release that same day, the company stated that the submission was Amgen's first "using the 351(k) biosimilar pathway" and that "[t]he active ingredient of ABP 501 is an anti-TNF-α monoclonal antibody that has the same amino acid sequence as adalimumab." Press Release, Amgen, "Amgen's First Biosimilar Biologics License Application For ABP 501 Submitted to U.S. Food And Drug Administration" (Nov. 25, 2016),

attached hereto as Exhibit 4. Amgen further stated that "ABP 501 has the same pharmaceutical dosage form and strength as adalimumab (U.S.) and adalimumab (EU)." *Id.*

50. Upon information and belief, the FDA accepted Amgen's aBLA for ABP 501 for review on January 22, 2016. Upon information and belief, the FDA has set a September 25, 2016 Biosimilar User Fee Act target action date.

51. Amgen represented to the FDA that its ABP 501 product is biosimilar to AbbVie's HUMIRA®. *See* Exhibit 2, at 8. As such, the BPCIA requires Amgen's aBLA Product to utilize the same mechanism of action as HUMIRA® for the conditions of use prescribed, recommended, or suggested in HUMIRA®'s FDA approved label. *See* 42 U.S.C. § 262(k)(2)(A)(i)(II); Exhibit 2, at 22. In addition, the route of administration, dosage form, and strength of Amgen's aBLA Product are the same as those of AbbVie's HUMIRA®. *See id.* § 262(k)(2)(A)(i)(I); Exhibit 2, at 35.

52. Amgen is seeking regulatory approval for the following indications: rheumatoid arthritis; plaque psoriasis; juvenile idiopathic arthritis in patients 4 years of age and older; psoriatic arthritis; ankylosing spondylitis; adult Crohn's disease; and ulcerative colitis. *See* Exhibit 2 at 22. On July 12, 2016, Amgen presented results from two Phase 3 studies conducted in moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis to FDA's Arthritis Advisory Committee. *See* Exhibit 2, at 14-21, 63-66.

53. Amgen has committed a statutory act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by submitting an application seeking approval of a biological product with respect to patents identified by AbbVie in the lists of patents described in 42 U.S.C. § 262(*l*)(3).

ABBVIE'S ADALIMUMAB PATENTS

54. In the course of developing HUMIRA®, AbbVie has obtained more than 100 patents related to HUMIRA®, including its administration, its formulation, and the processes for manufacturing it. Upon information and belief, including information produced by Amgen under 42 U.S.C. § 262(*l*)(2), the Amgen aBLA Product will infringe at least 61 AbbVie patents (the "AbbVie Patents"). These patents are listed in Exhibit 1. Because of Amgen's actions, AbbVie is limited to asserting the following 10 patents in the present lawsuit: U.S Patent No. 8,663,945; U.S Patent No. 8,911,964; U.S Patent No. 8,916,157; U.S Patent No. 8,961,973; U.S Patent No. 8,986,693; U.S Patent No. 9,096,666; U.S Patent No. 9,220,781; U.S Patent No. 9,272,041; U.S. Patent No. 9,359,434; and U.S. Patent No. 9,365,645.

U.S. Patent No. 8,663,945

55. U.S. Patent No. 8,663,945 (the "'945 Patent"), titled "Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture," was duly and legally issued by the Patent Office on March 4, 2014. A true and correct copy of the '945 Patent is attached as Exhibit 5.

56. AbbVie Inc. is the owner by assignment of the '945 Patent. AbbVie Biotechnology Ltd. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '945 Patent in the United States. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '945 Patent.

U.S. Patent No. 8,911,964

57. U.S. Patent No. 8,911,964 (the "'964 Patent"), titled "Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody," was duly and legally issued by the Patent Office on December 16, 2014. A true and correct copy of the '964 Patent is attached as Exhibit 6.

58. AbbVie Inc. is the owner by assignment of the ’964 Patent. AbbVie Biotechnology Ltd. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the ’964 Patent in the United States. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’964 Patent.

U.S. Patent No. 8,916,157

59. U.S. Patent No. 8,916,157 (the “’157 Patent”), titled “Formulation of Human Antibodies for Treating TNF-α Associated Disorders,” was duly and legally issued by the Patent Office on December 23, 2014. A true and correct copy of the ’157 Patent is attached as Exhibit 7.

60. AbbVie Biotechnology Ltd. is the owner by assignment of the ’157 Patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’157 Patent in the United States. AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’157 Patent.

U.S. Patent No. 8,961,973

61. U.S. Patent No. 8,961,973 (the “’973 Patent”), titled “Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders,” was duly and legally issued by the Patent Office on February 24, 2015. A true and correct copy of the ’973 Patent is attached as Exhibit 8.

62. AbbVie Biotechnology Ltd. is the owner by assignment of the ’973 Patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’973 Patent in the United States. AbbVie Inc. and AbbVie

Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’973 Patent.

U.S. Patent No. 8,986,693

63. U.S. Patent No. 8,986,693 (the “’693 Patent”), titled “Use of TNFα Inhibitor for Treatment of Psoriasis,” was duly and legally issued by the Patent Office on March 24, 2015. A true and correct copy of the ’693 Patent is attached as Exhibit 9.

64. AbbVie Biotechnology Ltd. is the owner by assignment of the ’693 Patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’693 Patent in the United States. AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’693 Patent.

U.S. Patent No. 9,096,666

65. U.S. Patent No. 9,096,666 (the “’666 Patent”), titled “Purified Antibody Composition,” was duly and legally issued by the Patent Office on August 4, 2015. A true and correct copy of the ’666 Patent is attached as Exhibit 10.

66. AbbVie Biotechnology Ltd. is the owner by assignment of the ’666 Patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’666 Patent in the United States. AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’666 Patent.

U.S. Patent No. 9,220,781

67. U.S. Patent No. 9,220,781 (the “’781 Patent”), titled “Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders,” was duly and legally issued by the

Patent Office on December 29, 2015. A true and correct copy of the ’781 Patent is attached as Exhibit 11.

68. AbbVie Biotechnology Ltd. is the owner by assignment of the ’781 Patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’781 Patent in the United States. AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’781 Patent.

U.S. Patent No. 9,272,041

69. U.S. Patent No. 9,272,041 (the “’041 Patent”), titled “Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders,” was duly and legally issued by the Patent Office on March 1, 2016. A true and correct copy of the ’041 Patent is attached as Exhibit 12.

70. AbbVie Biotechnology, Ltd. is the owner by assignment of the ’041 Patent. AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the ’041 Patent in the United States. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’041 Patent.

U.S. Patent No. 9,359,434

71. U.S. Patent No. 9,359,434 (the “’434 Patent”), titled “Cell Culture Methods to Reduce Acidic Species,” was duly and legally issued by the Patent Office on June 7, 2016. A true and correct copy of the ’434 Patent is attached as Exhibit 13.

72. AbbVie Inc. is the owner by assignment of the ’434 Patent. AbbVie Biotechnology Ltd. is exclusively licensed to import, have imported, manufacture, or have

manufactured products, and to use methods, that would infringe the ’434 Patent in the United States. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’434 Patent.

U.S. Patent No. 9,365,645

73. U.S. Patent No. 9,365,645 (the “’645 Patent”), titled “Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins,” was duly and legally issued by the Patent Office on June 14, 2016. A true and correct copy of the ’645 Patent is attached as Exhibit 14.

74. AbbVie Inc. is the owner by assignment of the ’645 Patent. AbbVie Biotechnology Ltd. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the ’645 Patent in the United States. AbbVie Biotechnology Ltd. and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’645 Patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 8,663,945

75. AbbVie incorporates by reference paragraphs 1-74 as if fully set forth herein.

76. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

77. Upon information and belief, the FDA accepted Amgen’s aBLA for review on January 22, 2016.

78. AbbVie included the ’945 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

79. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

80. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the ’945 Patent is a technical act of infringement of at least claims 1 – 5, 7, 9 – 16, 18, 20 – 27, 29, and 31 – 39 of the ’945 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C. § 262(*l*)(3)(C).

81. Based on publicly available information and information provided by Amgen under 42 U.S.C. § 262(*l*)(2)(A), AbbVie identified claims 1 – 5, 7, 9 – 16, 18, 20 – 27, 29, and 31 – 39 as part of its statement of infringement pursuant to 42 U.S.C. § 262(*l*)(3)(C) (*i.e.*, Amgen’s commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), will infringe the ’945 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents). Amgen’s failure to provide manufacturing information as required by the BPCIA, however, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of Amgen’s manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Amgen infringes

certain claims of the ’945 patent. Amgen has the burden of establishing that the Amgen aBLA Product was not made by the process claimed in the ‘945 Patent. *See* 35 U.S.C. § 295.

82. Amgen has knowledge of and is aware of the ’945 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

83. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen’s aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 5, 7, 9 – 16, 18, 20 – 27, 29, and 31 – 39 of the ’945 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

84. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States using methods claimed in the ‘945 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’945 Patent, either literally or under the doctrine of equivalents.

85. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML’s manufacture of the Amgen aBLA product directly infringes at least one claim of the ’945 Patent, either literally or under the doctrine of equivalents.

86. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’945 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured

and/or will manufacture the Amgen aBLA product for sale in the United States market using methods claimed in the ’945 patent.

87. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’945 Patent.

88. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product and/or the use of the claimed methods of the ’945 patent.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,911,964

89. AbbVie incorporates by reference paragraphs 1-88 as if fully set forth herein.

90. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

91. Upon information and belief, the FDA accepted Amgen’s aBLA for review on January 22, 2016.

92. AbbVie included the ’964 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

93. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

94. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA

Product prior to the expiration of the ’964 Patent is a technical act of infringement of at least claims 1 – 5, 9 – 16, 20 – 21, 23 – 26, and 29 – 30 of the ’964 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(*l*)(3)(C).

95. Based on publicly available information and information provided by Amgen under 42 U.S.C. § 262(*l*)(2)(A), AbbVie identified claims 1 – 5, 9 – 16, 20 – 21, 23 – 26, and 29 – 30 as part of its statement of infringement pursuant to 42 U.S.C. § 262(*l*)(3)(C) (*i.e*., Amgen’s commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), will infringe the ’964 patent under 35 U.S.C. § 271(a) and § 271(g), either literally or under the doctrine of equivalents). Amgen’s failure to provide manufacturing information as required by the BPCIA, however, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of Amgen’s manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Amgen infringes certain claims of the ’964 patent. Amgen has the burden of establishing that the Amgen aBLA Product was not and/or will not be made by the process claimed in the ’964 Patent. *See* 35 U.S.C. § 295.

96. Amgen has knowledge of and is aware of the ’964 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

97. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen’s aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and

belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 5, 9 – 16, 20 – 21, 23 – 26, and 29 – 30 of the ’964 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

98. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States using methods claimed in the ’964 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’964 Patent, either literally or under the doctrine of equivalents.

99. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML’s manufacture of the Amgen aBLA product directly infringes at least one claim of the ’964 Patent, either literally or under the doctrine of equivalents.

100. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’964 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market using methods claimed in the ’964 patent.

101. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’964 Patent.

102. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product and/or the use of the claimed methods of the ’964 patent.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,916,157

103. AbbVie incorporates by reference paragraphs 1-102 as if fully set forth herein.

104. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

105. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

106. AbbVie included the '157 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

107. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

108. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the '157 Patent is a technical act of infringement of at least claims 1 – 7, 10 –11, 15 – 16, and 18 – 30 of the '157 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(l)(3)(C).

109. Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), once its aBLA is approved by the FDA, will directly infringe at least claims 1 – 7, 10 –

11, 15 – 16, and 18 – 30 of the ’157 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

110. Amgen has knowledge of and is aware of the ’157 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

111. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen’s aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 7, 10 –11, 15 – 16, and 18 – 30 of the ’157 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

112. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States, has an affirmative intent to actively induce infringement by others of one or more claims of the ’157 Patent, either literally or under the doctrine of equivalents.

113. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML’s manufacture of the Amgen aBLA product directly infringes at least one claim of the ’157 Patent, either literally or under the doctrine of equivalents.

114. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’157 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market.

115. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’157 Patent.

116. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 8,961,973

117. AbbVie incorporates by reference paragraphs 1-116 as if fully set forth herein.

118. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

119. Upon information and belief, the FDA accepted Amgen’s aBLA for review on January 22, 2016.

120. AbbVie included the ’973 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

121. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product promptly upon receiving FDA approval to do so.

122. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the ’973 Patent is a technical act of infringement of at least

claims 1 – 30 of the ’973 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(*l*)(3)(C).

123. Amgen has knowledge of and is aware of the ’973 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

124. Amgen has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Amgen aBLA Product. Amgen’s offering to sell, sale, making, and/or importation of the Amgen aBLA Product, once the aBLA is approved by the FDA, would actively induce infringement of at least claims 1 – 30 of the ’973 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

125. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instructs patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA Product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’973 Patent, either literally or under the doctrine of equivalents.

126. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA Product according to Amgen’s proposed package insert and, therefore, will directly infringe at least one claim of the ’973 Patent, either literally or under the doctrine of equivalents.

127. Upon information and belief, Amgen knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’973 Patent, either literally

or under the doctrine of equivalents, by at least Amgen's proposed package insert for the Amgen aBLA Product.

128. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '973 Patent.

129. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 8,986,693

130. AbbVie incorporates by reference paragraphs 1-129 as if fully set forth herein.

131. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

132. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

133. AbbVie included the '693 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

134. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product promptly upon receiving FDA approval to do so.

135. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA

Product prior to the expiration of the ’693 Patent is a technical act of infringement of at least claims 1 – 8 of the ’693 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(*l*)(3)(C).

136. Amgen has knowledge of and is aware of the ’693 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

137. Amgen has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Amgen aBLA Product. Amgen’s offering to sell, sale, making, and/or importation of the Amgen aBLA Product, once the aBLA is approved by the FDA, would actively induce infringement of at least claims 1 – 8 of the ’693 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

138. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instructs patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA Product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’693 Patent, either literally or under the doctrine of equivalents.

139. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA Product according to Amgen’s proposed package insert and, therefore, will directly infringe at least one claim of the ’693 Patent, either literally or under the doctrine of equivalents.

140. Upon information and belief, Amgen knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '693 Patent, either literally or under the doctrine of equivalents, by at least Amgen's proposed package insert for the Amgen aBLA Product.

141. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '693 Patent.

142. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT VI

INFRINGEMENT OF U.S. PATENT NO. 9,096,666

143. AbbVie incorporates by reference paragraphs 1-142 as if fully set forth herein.

144. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

145. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

146. AbbVie included the '666 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

147. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

148. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the '666 Patent is a technical act of infringement of at least claims 1 – 30 of the '666 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(*l*)(3)(C).

149. Based on publicly available information and information provided by Amgen under 42 U.S.C. § 262(*l*)(2)(A), AbbVie identified claims 1 – 30 as part of its statement of infringement pursuant to 42 U.S.C. § 262(l)(3)(C) (i.e., Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), will infringe the '666 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents). Amgen's failure to provide manufacturing information as required by the BPCIA, however, has prevented AbbVie from learning additional facts that would support AbbVie's allegation. In the absence of Amgen's manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Amgen infringes certain claims of the '666 patent.

150. Amgen has knowledge of and is aware of the '666 Patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

151. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen's aBLA, and will

manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 30 of the '666 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

152. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States, has an affirmative intent to actively induce infringement by others of one or more claims of the '666 Patent, either literally or under the doctrine of equivalents.

153. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML's manufacture of the Amgen aBLA product directly infringes at least one claim of the '666 Patent, either literally or under the doctrine of equivalents.

154. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '666 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market.

155. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '666 Patent.

156. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 9,220,781

157. AbbVie incorporates by reference paragraphs 1-156 as if fully set forth herein.

158. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

159. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

160. AbbVie included the '781 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

161. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

162. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the '781 Patent is a technical act of infringement of at least claims 1 – 2, 4 – 6, 15 – 18, 20 – 22, 27, and 29 – 30 of the '781 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(*l*)(3)(C).

163. Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), once its aBLA is approved by the FDA, will directly infringe at least claims 1 – 2, 4 – 6, 15 – 18, 20 – 22, 27, and 29 – 30 of the '781 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

164. Amgen has knowledge of and is aware of the ’781 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

165. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen’s aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 2, 4 – 6, 15 – 18, 20 – 22, 27, and 29 – 30 of the ’781 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

166. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States, has an affirmative intent to actively induce infringement by others of one or more claims of the ’781 Patent, either literally or under the doctrine of equivalents.

167. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML’s manufacture of the Amgen aBLA product directly infringes at least one claim of the ’781 Patent, either literally or under the doctrine of equivalents.

168. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’781 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market.

169. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’781 Patent.

170. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 9,272,041

171. AbbVie incorporates by reference paragraphs 1-170 as if fully set forth herein.

172. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

173. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

174. AbbVie included the '041 Patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

175. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

176. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the '041 Patent is a technical act of infringement of at least claims 1 – 2, 4 – 7, 16 – 19, 21 – 23, and 28 – 30 of the '041 Patent under 35 U.S.C.

§ 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim by claim infringement contentions to Amgen pursuant to U.S.C.§ 262(l)(3)(C).

177. Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), once its aBLA is approved by the FDA, will directly infringe at least claims 1 – 2, 4 – 7, 16 – 19, 21 – 23, and 28 – 30 of the '041 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

178. Amgen has knowledge of and is aware of the '041 Patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

179. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen's aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 2, 4 – 7, 16 – 19, 21 – 23, and 28 – 30 of the '041 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

180. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States, has an affirmative intent to actively induce infringement by others of one or more claims of the '041 Patent, either literally or under the doctrine of equivalents.

181. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML's manufacture of the Amgen aBLA product directly infringes at least one claim of the '041 Patent, either literally or under the doctrine of equivalents.

182. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '041 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market.

183. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '041 Patent.

184. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 9,359,434

185. AbbVie incorporates by reference paragraphs 1-184 as if fully set forth herein.

186. Upon information and belief on November 25, 2015, Amgen submitted an aBLA to FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

187. Upon information and belief, the FDA accepted Amgen's aBLA for review on January 22, 2016.

188. AbbVie included the '434 Patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

189. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product promptly upon receiving FDA approval to do so.

190. Based on publicly available information and information provided by Amgen under 42 U.S.C. § 262(*l*)(2)(A), Amgen's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the '434 Patent is a technical act of infringement of at least claims 1 – 5, 7 – 21, and 23 – 30 of the '434 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. AbbVie has provided detailed, claim-by-claim infringement contentions to Amgen pursuant to U.S.C. § 262(*l*)(3)(C).

191. Based on publicly available information and information provided by Amgen under 42 U.S.C. § 262(*l*)(2)(A), AbbVie identified claims 1 – 5, 7 – 21, and 23 – 30 as part of its statement of infringement pursuant to 42 U.S.C. § 262(*l*)(3)(C) (*i.e.*, Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), will infringe the '434 Patent under 35 U.S.C. § 271(a) and § 271(g), either literally or under the doctrine of equivalents). Amgen's failure to provide manufacturing information as required by the BPCIA, however, has prevented AbbVie from learning additional facts that would support AbbVie's allegation. In the absence of Amgen's manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Amgen infringes certain claims of the '434 Patent.

192. Amgen has knowledge of and is aware of the ’434 Patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

193. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen’s aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 5, 7 – 21, and 23 – 30 of the ’434 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

194. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States using methods claimed in the ‘434 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’434 Patent, either literally or under the doctrine of equivalents.

195. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML’s manufacture of the Amgen aBLA product directly infringes at least one claim of the ’434 Patent, either literally or under the doctrine of equivalents.

196. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’434 Patent, either literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market using methods claimed in the ’434 patent.

197. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’434 Patent.

198. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product and/or the use of the claimed methods of the ’434 patent.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 9,365,645

199. AbbVie incorporates by reference paragraphs 1-198 as if fully set forth herein.

200. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

201. Upon information and belief, the FDA accepted Amgen’s aBLA for review on January 22, 2016.

202. AbbVie included the ’645 Patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

203. Upon information and belief, Amgen intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product upon receiving FDA approval to do so.

204. Based on confidential information disclosed to AbbVie by Amgen pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Amgen’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Amgen aBLA Product prior to the expiration of the ’645 Patent is a technical act of infringement of at least claims 1 – 7, 12 – 21, and 26 – 30 of the ’645 Patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

205. Amgen's commercial manufacture, use, sale, offer for sale, and/or importation of the Amgen aBLA Product (either directly or through its affiliate(s), subsidiary(s), and/or agent(s)), once its aBLA is approved by the FDA, will directly infringe at least claims 1 – 7, 12 – 21, and 26 – 30 of the '645 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

206. Amgen has knowledge of and is aware of the '645 Patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

207. Upon information and belief, AML manufactured the Amgen aBLA product for use in clinical trials, the results of which were submitted as part of Amgen's aBLA, and will manufacture the Amgen aBLA product once it is approved by FDA. Upon information and belief, Amgen Inc. acts in concert with and/or directs AML to make the Amgen aBLA Product, and thereby actively induces infringement of at least claims 1 – 7, 12 – 21, and 26 – 30 of the '645 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

208. Upon information and belief, Amgen Inc., by filing an aBLA that establishes that AML will manufacture the Amgen aBLA product for sale in the United States using methods claimed in the '645 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the '645 Patent, either literally or under the doctrine of equivalents.

209. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that AML's manufacture of the Amgen aBLA product directly infringes at least one claim of the '645 Patent, either literally or under the doctrine of equivalents.

210. Upon information and belief, Amgen Inc. knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '645 Patent, either

literally or under the doctrine of equivalents, by at least the fact that AML has manufactured and/or will manufacture the Amgen aBLA product for sale in the United States market using methods claimed in the '645 patent and/or the use of the claimed methods of the '645 patent.

211. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '645 Patent.

212. AbbVie is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA Product.

COUNT XI
VIOLATION OF 42 U.S.C. § 262(*l*)(8)(A)

213. AbbVie incorporates by reference paragraphs 1-212 as if fully set forth herein.

214. This claim arises under 42 U.S.C. § 262 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

215. 42 U.S.C. § 262(*l*)(8)(A) requires Amgen to provide notice to AbbVie "not later than 180 days before the date of the first commercial marketing" of the Amgen aBLA Product, which can only be given after FDA licensure.

216. Upon information and belief, on November 25, 2015, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA Product, a biosimilar version of adalimumab, which is subject to BLA No. 125057 to AbbVie Inc.

217. Upon information and belief, the FDA accepted Amgen's aBLA for ABP 501 for review on January 22, 2016, but such product has not been licensed by the FDA.

218. On June 12, 2016, AbbVie asked that Amgen confirm by no later than June 28, 2016, that Amgen would provide AbbVie with at least 180 days' notice of commercial marketing should it receive a license from the FDA.

219. Amgen failed to respond to AbbVie's request. Amgen's failure to respond suggests that it will refuse to comply with the notice provision of the BPCIA, which will injure AbbVie by depriving it of the procedural protections of the BPCIA and by subjecting it to the burden of unnecessary litigation.

220. Amgen's intended violation of the BPCIA has caused and will cause AbbVie injury, including irreparable harm for which AbbVie has no adequate remedy at law, and will continue unless the statutory requirement is declared and enforced by this Court.

221. AbbVie is entitled to an order compelling Amgen to comply with the notice of commercial marketing provision set forth in 42 U.S.C. § 262(*l*)(8)(A) and preliminary and/or permanent equitable relief enjoining any commercial manufacture, use, offer to sell or sale within the United States of Amgen's proposed biosimilar adalimumab product until 180 days after Amgen has provided a proper post-licensure notice of commercial marketing under the BPCIA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendants and grant the following relief:

a. a judgment that Amgen has infringed or induced infringement of one or more claims of the AbbVie Patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment that Amgen has or will infringe or has or will induce infringement of one or more claims of the AbbVie Patents by engaging in the manufacture, import, offer for sale,

sale, or use within the United States of the Amgen aBLA Product before the expirations of the AbbVie Patents;

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Amgen, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the AbbVie Patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the AbbVie Patents;

d. a declaration and order compelling Amgen to comply with the notice of commercial marketing provision set forth in 42 U.S.C. § 262(l)(8)(A) and preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Amgen, their officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from any commercial manufacture, use, offer to sell or sale within the United States of Amgen's proposed biosimilar adalimumab product until 180 days after Amgen has given proper post-licensure notice of commercial marketing under the BPCIA;

e. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

f. such other relief as this Court may deem just and proper.

Respectfully submitted,

ROSS ARONSTAM & MORITZ LLP

/s/ Benjamin J. Schladweiler
Benjamin J. Schladweiler (#4601)
Nicholas D. Mozal (#5838)
100 S. West Street, Suite 400
Wilmington, DE 19801
(302) 576-1600
bschladweiler@ramllp.com
nmozal@ramllp.com

Counsel for Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd.

Of Counsel:

William F. Lee
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
william.lee@wilmerhale.com

William G. McElwain
Amy K. Wigmore
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
william.mcelwain@wilmerhale.com
amy.wigmore@wilmerhale.com

Michael A. Morin
David P. Frazier
Casey L. Dwyer
LATHAM & WATKINS LLP
555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
michael.morin@lw.com
david.frazier@lw.com
casey.dwyer@lw.com

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